REMARKS

Claims 1-12 are pending in the above-identified application. Claims 1-12 as originally filed were copied from U.S. Patent No. 6,270,672 B1. Claims 1-12 were rejected on two grounds: 35 U.S.C. §102(b), and obvious-type double patenting. Claims 1 and 12 bave been amended to further clarify the subject matter therein, and claims 13-24 have been added. Applicant respectfully requests tbat the above referenced rejections be reconsidered and withdrawn.

I. OATH AND DECLARATION

Apparently referring to tbe hand corrected address of some of the inventors, the Office Action asserts that "Non-initialed and/or non-dated alternations have been made to the oath or declaration. See 37 CFR § 1.52(c)." The Office Action thus required a new oath or declaration.

The Office Action is incorrect in this objection. 37 CFR § 1.52(c) does not pertain to alterations to the oath or declaration. On the contrary, it applies only to the "application papers", not the declaration. In pertinent part it states, "[A]lteration to of application papers filed must be made before the signing of any *accompanying* oath or declaration ...." Use of the word "accompanying" clearly means that the term "application papers" does not include tbe oath or declaration. 37 CFR § 1.52(c) is silent as to corrections to the oath or dcclaration.

Moreover, the altered portions of the declarations, as objected to in the Office Action, and the inventors' addresses, are neither statutorily or by rule required to appear in the declaration. Title 35 contains no provision that the oath or declaration recite the inventors' addresses. *E.g.*, 35 U.S.C. § 115. And, 37 CFR § 1.63(c) provides, in effect, that the inventors' addresses can be provided in the declaration or in an application data sheet in accordance with 37 CFR § 1.76.

Admittedly, MPEP § 602.01 provides that "The wording of an oath or declaration cannot be amended, altered, or changed in any manner after it has been signcd ...." As noted above that procedurc finds no support in the statute or regulations. But more importantly, MPEP § 602.01 further states, "[I]n some cases, a deficiency in the oath or declaration can be corrected by a supplemental paper such as an application date sheet ... and a ncw oath or declaration is not necessary."

Since the inventors' addresses could have been initially submitted on the application data sheet, as MPEP § 602.01 permits, any deficiency in those addresses can be subsequently corrected by an application data sheet. Accordingly, Applicant respectfully submitted on December 22, 2003 a completed application data sheet that contains, among other data, the last known addresses of the inventors pursuant to 37 CFR 1.76.

II. DOUBLE PATENTING

Claims 1-12 stand rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-36 of commonly owned U.S. Patent No. U.S. Patent No. 6,464,851 B. The Examiner acknowledges that the claims are not identical.

A terminal disclaimer is properly used to overcome a rejection based on a nonstatutory double patent ground when the conflicting patent is shown to be commonly owned with the present application. 37 CFR 1.130(b); MPEP §804.02(II). The present application and the cited patent, U.S. Patent No. 6,464,851, were commonly owned and subject to an obligation of assignment to Gradipore at the time the present invention was made. As such, Applicant respectfully submitted a terminal disclaimer on December 22, 2003. The filing of a terminal disclaimer to obviate a rejection based on nonstatutory double patenting is not an admission of the propriety of the rejection. MPEP §804.02.

III. CLAIM REJECTIONS UNDER 35 USC §102

Claims 1-9, 11-12

Claims 1-9 and 11-12 are rejected under 35 U.S.C. §102(b) as being anticipated by Margolis, WO 94/22904 and claims 1-12 are rejected as being anticipated by Mullon, (article entitled Forced Flow electrophoresis of Proteins and Viruses"). Both Margolis and Mullon were cited as anticipating references in the parent application (Ser. No. 09/470,823), which ultimately issued as U.S. Patent No. 6,464,851. Applicant respectfully traverses on substantially the same grounds set forth in Applicant's response to office action, filed on March 21, 2001 in the parent application, as well as the oral arguments heard by the examiner during the telephonic interview of May 23, 2001 (and summarized

in Applicant's supplemental response to office action filed on May 30, 2001). Claims 1-12 have been to incorporate the claim limitation, *i.e,* "substantially all transmembrane migration of the pathogen or pharmaceutically active molecule is initiated by application of current", which the Examiner has already determined with respect to the parent case that Mullon teaches a forced flow system and does not teach the claimed limitation. Moreover, as noted at greater length in the March 21, 2001 response to office action, page 16, Margolis did not contemplate separation of particles such as viruses, prions or bacteria that are extremely small as compared to macromolecules. There is no teaching or suggestion in Margolis that its system may be adapted or applied to the removal of infectious agents from samples. Such pathogens under conventional thinking would not be expected to act in a similar manner as small molecules or macromolecules. Accordingly, Applicant respectfully requests that rejection on this basis be reconsidered and withdrawn.

Claims 13-24

Claims 13-24 have been added and are supported by the specification. Both the Margolis and Mullon references fail to disclose each and every limitation found in claims 13-24, and therefore cannot anticipate for at least the following additional reasons.

First, Margolis does not disclose a separation means "containing a selective membrane that allows passage of either a pathogen or a pharmaceutically active molecule through the membrane, while preventing the other from entering therethrough," as required by the present claims. By contrast, Margolis requires that the macromolecules being separated both enter the separation medium or membrane. Margolis, claim 1 and pg. 3, ln. 25-34 ("applying an electrophoretic potential ... to drive the macromolecules of the mixture into the medium until at least a proportion of the at least once species of macromolecules emerges from the medium...and the other species of macromolecules have penetrated a substantial distance through the medium..."); *see also* Margolis, pg. 6, ln. 13-34. In claims 13-24, application of a current and a selective membrane allows passage of either a pathogen or a pharmaceutically active molecule through the membrane, while preventing the other (e.g., the remaining pathogen or a pharmaceutically active molecule) from entering the separation means. Indeed, Margolis requires the reversing of the polarity of the electrophoretic

potential so as to drive the macromolecules which enter the separation medium back towards the first electrolyte solution in order to effect separation. *See* Margolis, pg. 13, ln. 25-30. This is not required for the present claims. As Margolis does not disclose each and every limitation contained in claims 13-24, it cannot anticipate.

Second, the Mullon reference fails to disclose each and every limitation found in claims 13-24, and therefore also cannot anticipate. Mullon fails to disclose a (1) "selective membrane" or a selective membrane that (2) "allows passage of either a pathogen or a pharmaceutically active molecule through the membrane, while preventing the other from entering therethrough". Instead, Mullon teaches away from the use of a selective membrane and discloses "a model for forced-flow electrophoresis (FFE)" which makes use of nonselective membranes irrespective of pore size. *See* Mullon, pg. 123 (Abstract); *see also* Mullon, pg. 123 ("During electroultrafiltration and cross-flow electrophoresis, one of the discriminating factors is the membrane pore size, whereas forced-flow electrophoresis (FFE) makes use of nonselective membranes that prevent membrane polarization."); *see also* Mullon, pg. 126 ("...the absence of selectivity of the membrane prevents gel polarization"). Indeed, Mullon discloses a solute separation method *without* the use of "a selective membrane" or a selective membrane that "allows passage of either a pathogen or a pharmaceutically active molecule through the membrane, while preventing the other from entering therethrough," which are both required limitations in independent claims 13 and 24, and incorporated in claims 14-23. Without teaching these limitations, Mullon cannot anticipate claims 13-24.

CONCLUSION

In view of the foregoing amendments and arguments, Applicant respectfully submits that the claims are in condition for allowance. If the Examiner has any questions regarding this Response to Office Action or the Application in general, the Examiner is invited to contact the Applicant's attorney at the below listed telephone number. While the fees for a three-month extension of time and for a terminal disclaimer were already paid on December 22, 2003, if the Commissioner determines that any additional fees are due, please charge our Deposit Account No. 02-0393.

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Respectfully submitted,

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